

January 2002



Minnesota Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

University Park Plaza
2829 University Ave SE, Suite 530
Minneapolis, MN 55414-3251
www.phcybrd.state.mn.us

Disciplinary Actions

No formal disciplinary actions were concluded by the Minnesota Board of Pharmacy, during the period September 1, 2001, through November 30, 2001.

Notice of Intent to Adopt Rules Without a Public Hearing

Proposed Amendment to Rules Relating to Lighting Standards, Patient Counseling, Internship, Controlled Substance Rescheduling, Expiration Dates, and Lunch Breaks for Pharmacists, Minnesota Rules, 6800.0100 et seq.

Introduction. The Board of Pharmacy intends to adopt rules without a public hearing following the procedures set forth in the Administrative Procedure Act, *Minnesota Statutes*, sections 14.22 to 14.28, and rules of the Office of Administrative Hearings, *Minnesota Rules*, parts 1400.2300 to 1400.2310. You may submit written comments on the proposed rules and may also submit a written request that a hearing be held on the rules until February 15, 2002.

Agency Contact Person. Comments or questions on the rules and written requests for a public hearing on the rules must be submitted to the agency contact person. The agency contact person is David Holmstrom at the Minnesota Board of Pharmacy, 2829 University Ave SE, Suite 530, Minneapolis, MN 55414-3251, phone: 612/617-2201, fax: 612/617-2212.

Subject of Rules and Statutory Authority. The proposed rules are about lighting standards, patient counseling, internship, controlled substance rescheduling, expiration dates, and lunch breaks for pharmacists. The statutory authority to adopt the rules is *Minnesota Statutes*, section 151.06 and 152.02. The proposed rule package establishes minimum lighting standards for prescription dispensing areas of a pharmacy, expands the patient counseling standards of OBRA 90 to all patients, not just Medicaid patients, schedules or reschedules several controlled substances in order to bring Minnesota's requirements into conformity with federal requirements, amends expiration date limits on repackaged drugs to conform with USP standards, provides authorization of lunch or rest breaks for pharmacists, and repeals an obsolete section of the rules (6800.7520 subp. 1 G) relating to dispensing of drugs from hospital emergency rooms. A free copy of the rules proposed for change is available upon request from the agency contact person listed above or from the Board's Web site at www.phcybrd.state.mn.us.

Comments. You have until 4:30 PM on February 15, 2002, to submit written comments in support of or in opposition to the proposed rules and any part or subpart of the rules. Your com-

ments must be in writing and received by the agency contact person by the due date. Comments are encouraged. Your comments should identify the portion of the proposed rules addressed and the reason for the comments. You are encouraged to propose any change desired. Any comments that you would like to make on the legality of the proposed rules must also be made during this comment period.

Request for a Hearing. In addition to submitting comments, you may also request that a hearing be held on the rules. Your request for a public hearing must be in writing and must be received by the agency contact person no later than 4:30 PM on February 15, 2002. Your written request for a public hearing must include your name and address. You must identify the portion of the proposed rules to which you object or state that you oppose the entire set of rules. Any request that does not comply with these requirements is not valid and cannot be counted by the agency when determining whether a public hearing must be held. You are also encouraged to state the reason for the request and any changes you want made to the proposed rules.

Withdrawal of Requests. If 25 or more persons submit a valid written request for a hearing, a public hearing will be held unless a sufficient number withdraw their requests in writing. If enough requests for a hearing are withdrawn to reduce the number below 25, the agency must give written notice of this to all persons who requested a hearing, explain the actions the agency took to effect the withdrawal, and ask for written comments on this action. If a public hearing is required, the agency will follow the procedures in *Minnesota Statutes*, sections 14.131 to 14.20.

Modifications. The proposed rules may be modified as a result of public comments. The modifications must be supported by comments and information submitted to the agency, and the adopted rules may not be substantially different than these proposed rules. If the proposed rules affect you in any way, you are encouraged to participate in the rule-making process.

Statement of Need and Reasonableness. A statement of need and reasonableness is now available from the agency contact person. This statement contains a summary of the justification for the proposed rules, including a description of who will be affected by the proposed rules and an estimate of the probable cost of the proposed rules. Copies of the statement may be obtained at the cost of reproduction from the agency.

Adoption and Review of Rules. If no hearing is required, the agency may adopt the rules after the end of the comment period. The rules and supporting documents will then be submitted to the

Continued on page 4



National Pharmacy

(Applicability of the contents of articles in the National Pharmacy Com assumed and can only be ascertained by examin

CDER Drug Preparedness and Response to Bioterrorism Web Page

To help prepare the country for possible bioterrorism attacks, the US Food and Drug Administration (FDA) is working with other federal agencies to ensure that adequate supplies of medicine and vaccines are available to the American public. FDA's Center for Drug Evaluation and Research (CDER) created a Web site at www.fda.gov.cder/ that provides links to the most current information on drug therapy and vaccines, plus advice on purchasing and taking medication.

The site provides detailed information about Cipro®, doxycycline, penicillin G, and the anthrax vaccine, frequently asked questions, and links to the US Department of Health and Human Services, the Centers for Disease Control and Prevention, and the National Library of Medicine Web sites.

DEA "Pharmacist's Manual" Available

The US Drug Enforcement Administration (DEA) announced that the *Pharmacist's Manual, An Information Outline of the Controlled Substances Act of 1970* is available in print. According to DEA, all field offices will be provided copies of the *Pharmacist's Manual* for distribution. Pharmacists interested in obtaining printed copies should contact their local DEA office. Telephone numbers for DEA offices are on the DEA Diversion Control Web site at www.dea diversion.usdoj.gov under "Offices and Directories." Requests for 200 or more copies can be submitted in writing to the Liaison Unit (ODLL), DEA, Washington, DC 20537.

The *Pharmacist's Manual* is also posted on the DEA's Web site in a PDF format. The DEA plans to provide the *Pharmacist's Manual* on mini CD-Roms in the near future.

FDA Announces Changes to Accutane Pregnancy Risk Management Program

The Food and Drug Administration (FDA) recently announced significant changes to the Accutane® risk management program for pregnancy prevention. The new program, called S.M.A.R.T.™ (System to Manage Accutane® Related Teratogenicity), was developed in consultation with the FDA by Accutane's manufacturer, Hoffmann-La Roche Inc. The program is designed to enhance the safe and appropriate use of Accutane.

Detailed information about the program will be mailed to physicians, pharmacists, and 65,000 pharmacies on January 2, 2002, and physicians, pharmacists and patients must be in compliance with the program by April 10, 2002.

The S.M.A.R.T. program partners Accutane prescribers, patients, and pharmacists in an effort to prevent fetal exposure. Specifically, the program requires the following:

- ◆ Prescribers must read the S.M.A.R.T. "Guide to Best Practices" provided by Roche, and then sign and return to Roche the Letter of Understanding documenting their knowledge of the measures to minimize fetal exposures to Accutane. The manufacturer has also developed educational materials for prescribers and nurses. Prescribers will then receive from Roche special yellow self-adhesive Accutane Qualification Stickers. All prescriptions for Accutane should have the special yellow sticker attached to the prescriber's regular prescription form. This sticker will indicate to the pharmacist that the patient is "qualified" according to the new package insert, which means that the female patient has had negative pregnancy tests as indicated below, as well as education and counseling about pregnancy prevention. The pregnancy test will be repeated every month throughout the Accutane treatment course, and no prescriptions for more than a one-month supply of Accutane should be given at a time.
- ◆ All female patients must have two negative urine or serum pregnancy tests before the initial Accutane prescription is written, and for each month of therapy they must have a negative pregnancy test result before receiving their next prescription, regardless of whether they are sexually active. All female patients must also select and use two forms of effective contraception simultaneously for at least one month prior to initiation of Accutane therapy, during therapy, and for one month following discontinuation of therapy unless they have had a hysterectomy or commit to absolute abstinence. They must sign a Patient Information/Consent form about Accutane and birth defects. Finally, female patients must be given the opportunity to enroll in the Accutane Survey. This confidential Survey, which has been going on for many years, collects data to help Roche and FDA decide if S.M.A.R.T. is helping to prevent exposure of unborn babies to Accutane. Patients who agree to participate in

Compliance News

Compliance News to a particular state or jurisdiction should not be construed as an endorsement of the law of such state or jurisdiction.)



the Survey will be making a major contribution to the public health .

- ◆ Pharmacists will dispense Accutane only upon presentation of a prescription with the special yellow Accutane Qualification Sticker. Pharmacists will dispense a maximum one-month supply of Accutane, fill prescriptions within seven days from the date of “qualification,” and provide a Medication Guide for patients with each Accutane prescription. Requests for refills (ie, more Accutane without a new prescription) or computerized or phoned-in prescriptions will not be filled.

To measure the effectiveness of the S.M.A.R.T. program, Roche will use several independent outcome assessment approaches. These include the Accutane Survey, conducted by the Slone Epidemiology Unit of Boston University School of Public Health, and an independent audit of pharmacies to assess the use of Accutane Qualification Stickers by prescribers. Prescribers, patients, and pharmacists all must participate fully in these critically important measures to ensure that fetal exposure to this potent teratogen does not occur.

Exposure of an unborn baby to Accutane is a serious adverse event and should be reported to Roche or directly to the FDA MedWatch Program. The contacts are as follows: Roche Medical Services 1-800-526-6367 or FDA MedWatch program 1-800-FDA-1088. MedWatch can also be accessed via the Internet at www.fda.gov/medwatch/index.html.

Pharmacists and Pharmacy Technicians Unknowingly Provide Personal Information to Data Collection Organizations

NABP recently learned of efforts by data collection organizations to collect personal information from pharmacists and pharmacy technicians. In an effort to promote continuing education (CE) materials or professional journals, representatives of these organizations are apparently contacting pharmacies to verify or request the names of employees. Some pharmacists and technicians have mistakenly assumed these calls are coming from the boards of pharmacy, believing the board is verifying the completion of required CE credits. Most likely, these calls did not originate from the board of pharmacy office. If a board contacts your pharmacy, board representatives will clearly

identify themselves as such. In general, state boards do not contact licensees by phone to verify CE credits .

DEA Forms Available on Web Site

The US Drug Enforcement Administration (DEA) recently announced the availability of selected reports and applications required by the federal Controlled Substances Act on the DEA Web site at www.deadiversion.usdoj.gov. The following forms are currently available:

DEA Form Description

41	Registrants' Inventory of Drugs Surrendered
106	Report of Theft or Loss of Controlled Substance
161	Application for Permit to Export Controlled Substances
189	Application for Individual Manufacturing Quota
224A	Renewal Application for Registration – Retail
225	New Application for Registration – Wholesale
225A	Renewal Application for Registration – Wholesale
236	Controlled Substances Import/Export Declaration
250	Application for Procurement Quota for Controlled Substances
357	Application for Permit to Import Controlled Substances
363	New Application for Registration – Narcotic Treatment Program
363A	Renewal Application for Registration – Narcotic Treatment Program
486	Import/Export Declaration – Chemical
510	New Application for Registration – Chemical
510A	Renewal Application for Registration – Chemical

The forms are available in PDF format, so it will be necessary to have Adobe Acrobat or Adobe Acrobat Reader installed on your computer. Two versions of each form will be available:

- 1) an interactive version, which will allow the user to complete the form online and print it on his or her printer for signature and mailing; and
- 2) a blank form, which can be printed and completed manually.

The DEA recommends completing the form online to reduce errors.

Continued from page 1

Office of Administrative Hearings for review for legality. You may ask to be notified of the date the rules are submitted to the office. If you want to be notified, or want to receive a copy of the adopted rules, or want to register with the agency to receive notice of future rule proceedings, submit your request to the agency contact person listed on page one.

Proposed Rule Changes

Minn. Rule 6800.0700. In this rule, under subpart 1, the Board is proposing to add an item "F" that establishes a minimum lighting level of 75-foot candles measured in the major work areas of the prescription department. Poor lighting, while relatively rare among Minnesota pharmacies, is a contributing factor to medication dispensing errors. As a result, the Board is taking this step to ensure a minimum lighting level in all prescription departments.

Minn. Rule 6800.0910. In this rule the Board is eliminating the differentiation between Medicaid and non-Medicaid patients regarding the patient counseling and DUR provisions of OBRA 90. Minnesota is one of fewer than 10 states that have not expanded the patient counseling and DUR provisions of OBRA 90 to all patients. The Board believes that it is now time to provide a uniform level of pharmacy services to all patients in Minnesota, regardless of socioeconomic status.

Minn. Rule 6800.2150. Under this proposal, a pharmacist working as the only pharmacist on duty may, at his or her option, leave the prescription department for a 30-minute lunch break without requiring all ancillary personnel to exit the prescription department and without locking the prescription department. The pharmacist would not be able to leave the building for the lunch break but would not be required to remain in the prescription department.

Any work done by a pharmacy technician during the pharmacist's absence would need to be checked by the pharmacist upon returning from lunch. During the pharmacist's temporary absence, no prescription medication may be provided to a patient or a patient's agent, unless the medication is a refill that the pharmacist has checked and released for furnishing to the patient and for which the pharmacist has determined that consultation by the pharmacist is not required.

This proposal is virtually identical to language currently in place in California and at least 15 other states. At last report, no problems associated with pharmacist lunch breaks have been reported.

Minn. Rule 6800.3110. Here, as in Minn. Rule 6800.0910, the Board is simply removing the differentiation between Medicaid

patients and non-Medicaid patients, insofar as the requirements of OBRA 90 are concerned.

Minn. Rule 6800.3350. Here, in subpart 3, the Board is proposing to change the expiration date of unit of use on blister card packaging done by pharmacists to a one-year expiration date from the date of packaging. This change conforms to a change in expiration date standards by the US Pharmacopeia.

Minn. Rules 6800.4210, 4220, 4230 and 4240. These sections are proposed for amendment as part of the scheduling and rescheduling of various controlled substance drugs, in order to bring Minnesota's controlled substance schedules into conformity with federal schedules.

Minn. Rule 6800.5300 and 5400. The Board is proposing some changes relating to internship. In the first instance, the Board is eliminating reference to the internship competency examination, which has been discontinued and is inserting reference to an internship manual, which has been developed by the Board's Internship Advisory Committee as a replacement for the internship competency examination.

The Board is also proposing to phase in a change in the total number of hours of internship required prior to licensure and the make-up of those hours. By the spring of 2003, the Board is proposing that students obtain a total of 1,600 hours of internship with 800 of those hours being required through PharmD clinical rotations and the remaining 800 being of a traditional compounding, dispensing, and patient counseling nature.

Minn. Rule 6800.7520. The Board is eliminating the requirement that hospital pharmacists develop a system allowing drug dispensing out of hospital emergency rooms in the absence of pharmacists and physicians. Statutory changes made by the legislature over the past few years have eliminated the need for this provision in Board rules.

Page 4 – January 2002

The *Minnesota Board of Pharmacy News* is published by the Minnesota Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

David E. Holmstrom, JD, RPh - State News Editor

Carmen A. Catizone, MS, RPh - National News Editor & Executive Editor

Courtney M. Karzen - Editorial Manager

Presorted Standard
U.S. Postage
PAID
Chicago, Illinois
Permit No. 5744

National Association of Boards of Pharmacy Foundation, Inc
700 Busse Highway
Park Ridge, Illinois 60068
MINNESOTA BOARD OF PHARMACY